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(54) Stents and stent delivery devices

(57) According to an aspect of the invention there are provided delivery devices (11, 12) for delivering a medical stent (120) to a treatment site for forming a conduit between a blood vessel and a heart chamber. The delivery devices comprise a hollow cylindrical body (100, 140) having a proximal end and a distal end, the stent being positioned within the body; and an actuator (110, 150) for expelling the stent from the body to form the conduit. Several stents for use with the delivery devices are also disclosed.

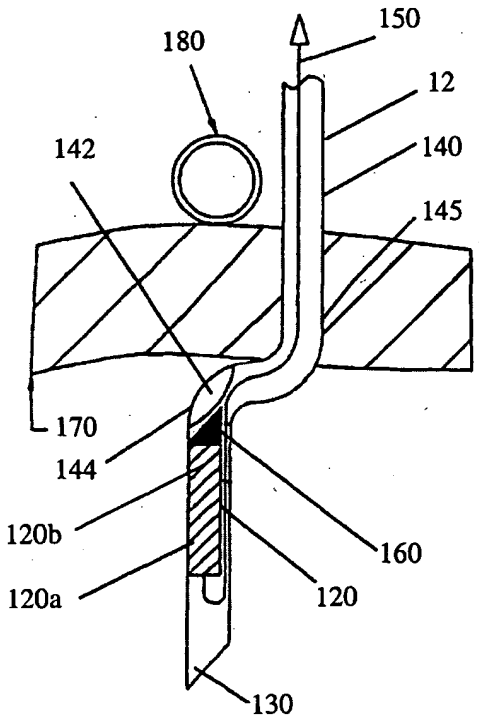

FIGURE 12

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Description

[0001] The present invention relates generally to a medical device and more particularly to a transthoracic stent and transthoracic stent delivery devices.

[0002] Heart disease is caused by a build-up of cholesterol fats and/or atherosclerotic plaque and/or atherosclerotic lesions within coronary arteries. Over time these lesions grow, progressively narrowing the arteries, thereby restricting the quantity of blood flowing through the artery. Atherosclerosis can lead to myocardial infarction, angina pectoris and/or possibly also be a contributing factor inducing strokes. Heart disease is one of the leading causes of death throughout the world. Those who survive the consequences of heart disease generally experience prolonged suffering and possibly also disability.

[0003] Percutaneous transluminal coronary angioplast (PTCA) is a technique used to clear occluded coronary arteries. Generally a stent is permanently placed within a vessel to hold the lumen open after PTCA, thus reinforcing the vessel wall and improving blood flow. Typically, a stent is a cylindrical shaped device formed from metal or polymers. One form of stent is radially compressed to a diameter that is smaller than that of the vessel in which it is to be deployed to enable it to be delivered to the treatment site. Once the stent has been delivered to the treatment site, it is expanded radially to allow it to contact and support the vessel wall. This type of stent can be crimped onto an expansion device such as a balloon catheter for delivery. Other stent types are fabricated elastically to resist compression in a free state and are releasably compressed for delivery. Both types of stent are expanded radially at the treatment site. Problems can arise if the stent does not fully expand, as the position of the stent may promote the formation of undesirable thrombi. Balloon angioplasty is a procedure in which PTCA is performed and a stent is deployed at the treatment site using a balloon catheter.

[0004] Typically, introduction of a stent that elastically resists compression involves introduction of a guidewire percutaneously. The guidewire is then steered to the treatment site through the vascular system. The stent is provided on the distal end of a catheter, which is advanced over the guidewire to the treatment site. The stent is deployed at this site, providing support to a damaged and/or collapsed vessel wall. The radially expandable stent is introduced in a similar manner, however the stent is crimped onto a balloon positioned at the distal end of the catheter and deployment of the stent at the treatment site is effected by inflation of the balloon. A similarly introduced stent could also be used to repair a dissection of a vessel or an aneurysm. Other problems may arise, if gradually over time the stent moves from its original position at the treatment site leaving a weak and vulnerable area of the vessel exposed.

[0005] Worldwide figures estimate that approximately 110 million people suffer from diabetes. Recent projections suggest that this figure will have doubled in 10 years. One of the consequences of diabetes is that the blood vessel walls are thinner, consequently the vessels are weaker. Studies have indicated that diabetic patients are more likely to suffer follow-on post balloon angioplasty complications with a five-year mortality rate of approximately 35%. Conversely diabetic patients who have undergone bypass surgery have a five-year mortality rate of 19%. However bypass surgery typically involves considerable trauma, pain and long periods of convalescence.

[0006] It is desirable to combine the advantage of coronary artery bypass surgery with the minimally invasive angioplast/stent delivery technique.

[0007] Typically coronary artery bypass graft surgery requires open-chest surgery, which involves an eight to ten-inch incision made in the chest, a thoracotomy. A variety of minimally invasive cardiac surgical techniques have been developed such as da Vinci. The da Vinci technique involves robotically assisted surgery requiring only three pencil-sized holes made between the ribs. Through these holes, two robotic-arms and an endoscope (a tiny camera) gain access to the heart, making surgery possible without opening the chest. Coronary artery bypass graft surgery (CABG) is the most commonly performed "open heart" operation. There are approximately 375,000 CABG surgeries performed in the United States each year. Studies show that patients who have minimally invasive operations are released from hospital one to two days earlier than patients recovering from conventional cardiac surgery. Other advantages of minimally invasive surgery can include quicker patient recovery times, less pain, and significantly less scarring than traditional open-heart operations.

[0008] However, adoption of new techniques such as the de Vinci technique is typically slow as the specific skill requirements are difficult to acquire and the techniques are more difficult to perform than the traditional by-pass surgery. Many of the new techniques involve direct vascularisation from the ventricle of the heart.

[0009] Numerous devices and delivery systems that facilitate these new techniques are disclosed in the prior art.

[0010] US 6,113,630 discloses an L-shaped transmyocardial implant, one leg of the L-shaped implant inserts into the coronary artery whilst the other leg inserts into the left ventricle of the heart through the myocardium. The portion of the implant that is positioned in the myocardium has a fabric cuff encircling the exterior surface that is used to integrate the implant with the myocardium and help prevent migration of the implant.

[0011] WO 00/15148 discloses a transmyocardial stent that provides a bypass around an occlusion in a coronary artery. The conduit has a section of a blood vessel attached to its interior lumen. Preferably, the section of blood vessel includes at least one naturally occurring one-way valve to prevent the backflow of blood from the coronary artery into the heart chamber.

[0012] WO 01/10348 discloses a method and apparatus relating to a conduit placed in the heart wall between the left ventricle and the coronary artery.

[0013] WO 00/21461 discloses devices and methods for delivering conduits into the wall of a patient's heart to communicate a coronary vessel with a heart chamber. The device includes a conduit support member which may be in the form of a shaft having a step which defines a recessed portion that receives the conduit. The conduit is covered by a sheath to protect tissue and/or the conduit during its delivery into the heart wall. The sheath is preferably tapered to aid in dilating the opening in the heart wall. The device preferably includes a dilator having a sharpened end and an enlarged end configured to be grasped to manipulate the dilator. There is also an actuator for allowing the sheath to be selectively moved to expose the conduit. The actuator includes a spring for biasing the sheath in a proximal direction.

[0014] The present invention seeks to provide an improved delivery system comprising a stent delivery device and stents for use therewith.

[0015] Accordingly, in a first aspect, the present invention provides a medical stent delivery device for delivering a stent to a treatment site, for forming a conduit between an occluded blood vessel and a heart chamber, the delivery device comprising a hollow cylindrical body having a proximal end and a distal end, said cylindrical body being capable of receiving a stent and actuator means operable for expelling the stent from the stent delivery device whereby, in use, the stent is positioned within the cylindrical body and on activation of the actuator means, the stent is expelled from the cylindrical body to form the conduit.

[0016] Ideally, the actuator means comprises a plunger mechanism. Conveniently, the stent is expelled from within the hollow cylindrical body by compression of the plunger mechanism.

[0017] The actuator means can be a manual plunger mechanism or an automated hydraulic or a LVDT type device. The actuator means, regardless of its mode of power, is required to actuate the expulsion of the stent.

[0018] Alternatively, the actuator means comprises a push-pull wire. Preferably, a 'flat' profile push-pull wire or such like may be used to push the stent into the desired position. The push-pull wire may be of a generally 'U' shaped profile and resides at the internal wall of the cylindrical body and provides maximum force transmission within the restricted bore of the cylindrical body. The push-pull wire may be made from a spring steel or similar material e.g. Nitinol.

[0019] A conical or bullet shaped tip (obdurator) provided on the distal tip of the profiled push-pull wire is of a suitable profile such that it promotes progression of the stent through the myocardium whilst also permitting perforation of the posterior wall of the coronary artery, causing no damage to the anterior artery wall.

[0020] The stent is radially expandable to form a sealed conduit between the heart and the vessel.

[0021] The hollow, substantially cylindrical body of the stent delivery device may have any suitable configuration, including in a first embodiment, a straight configuration and in a second embodiment, a substantially curved configuration. Ideally, in the second embodiment, the body comprises a substantially elbow-shaped curve and preferably the body has a generally S-shaped configuration.

[0022] Ideally, the device includes an opening in the cylindrical body, proximate the elbow-shaped curve through which opening, the stent is deployed.

[0023] Ideally, the device comprises a first puncture means deployed proximate the distal end of the cylindrical body. Conveniently, the first puncture means may be made from a plastics material.

[0024] Thus in the first embodiment with the cylindrical body of the medical stent delivery device having a straight configuration, the distal end of the hollow cylindrical body of the medical stent delivery system has a puncture means, optionally comprising a puncture needle. The puncture needle may be manufactured from stainless steel such as 316L or from a stiff thin walled high modulus plastic e.g. LCP. Ideally, the medical stent delivery device is used to gain access to the treatment site via a minimally invasive incision made through the patient's chest wall close to the treatment site. An introducer may be employed to provide access to the thoracic area for the delivery system and for other instruments, such as an endoscope.

[0025] Advantageously, the device in the second embodiment, includes a second puncture means deployed proximate the proximal end of the stent.

[0026] Ideally the distal end of the medical stent delivery system is advanced through the wall of the heart, the myocardium, to provide access to a heart chamber to obtain a supply of oxygenated blood. Use of a pressure-sensing device will indicate when the distal end of the medical stent delivery system has advanced sufficiently through the wall of the vessel into the chamber of the heart. Ideally, the stent is deployed in the myocardium using the actuator means with the distal end of the stent extending through to the heart chamber and the proximal end of the stent projecting out of the myocardial wall to the exterior of the heart. The proximal end of the stent is prevented from radially expanding by use of a sheath mechanism to hold the stent in a radially compressed state. Next an incision is made in the occluded vessel distal to the occlusion and the proximal end of the stent is inserted into this incision, thus forming a conduit between the heart chamber and the occluded vessel to allow oxygenated blood to flow into the vessel bypassing the occlusion.

[0027] Once the stent is in position the incision in the vessel is repaired using conventional techniques such as a suture or fibrin plug.

[0028] Advantageously, in the second embodiment in which the medical stent delivery system has a curved configuration, preferably a generally S-shaped configu-

ration, the medical stent delivery device gains access to the treatment site via a minimally invasive type incision close to the treatment site. It is preferable for another instrument to make this incision.

[0029] Ideally, an incision is made through the myocardium using the first puncture means positioned at the distal end of the hollow cylindrical body of the medical stent delivery device. Advantageously, a pressure-sensing device is used to indicate when the distal end of the medical stent delivery device has advanced sufficiently through the wall of the vessel into the chamber of the vessel.

[0030] The distal end of the medical stent delivery system is advanced through the myocardium into the heart chamber. Ideally the stent is deployed using actuation means through an orifice provided in the S-shaped hollow cylindrical body, preferably on an arcuate section (elbow) of the hollow cylindrical body.

[0031] Advantageously, the stent is prevented from expanding radially by use of a retaining sheath. In the second embodiment in which the delivery device has a generally S-shaped configuration, the proximal end of the stent includes a puncture device. This puncture device makes an incision through the myocardium and then into the diseased, occluded vessel, ideally distal to the occlusion. Once it is established that the stent is in the correct position, the sheath is removed thereby enabling the stent to expand radially thus forming a conduit between the occluded vessel and the heart chamber (preferably, the left ventricle). The S-shaped device is also suitable to operate in this manner even if the diseased, occluded vessel is temporarily shifted to one side in an operating technique which may be employed by a surgeon.

[0032] The function of the generally S-shaped-shaped puncture needle device and integral stent delivery system of the present invention is to deploy a stent through the posterior coronary artery wall and the myocardium into a chamber of the heart. With the exception of the location where the stent perforates the posterior coronary artery wall, the generally S-shaped puncture needle device and integral stent delivery system cause minimal trauma to the artery and no dissection or perforation of the anterior artery wall i.e. that wall interfacing with the pericardium. The device is minimally invasive and applicable predominantly to bypassing occlusions of the left anterior descending artery (LAD) or the right coronary artery on the beating heart via a parasternal or left anterior small thoracotomy. Insertion tools, stabilisers and thorascopic devices are required to carry out the procedure and visualisation may be conventional or video-assisted.

[0033] Multiple polypropylene stay sutures may be placed on both edges of the fatty epicardium, and these epicardial stay sutures are fixed to immobilise the area in which the puncture needle is to be inserted.

[0034] A wide angled endoscope is employed to position the puncture needle distal of the occlusion and in the correct position longitudinally relative to the coronary artery.

[0035] An automated or manual mechanism may be used to promote the puncture needle through the myocardium, and a pressure detector may be used to indicate that depth at which the myocardium is breached as the needle enters the left ventricle.

[0036] The position of the puncture needle and coronary artery relative to one another and the proposed path for the deployment of the stent are then checked.

[0037] Assuming the position of the puncture needle and the aperture for deployment of the stent are correct, an automated or manual mechanism operates the 'flat' profile 'U' push-pull wire to deploy the stent in the desired position.

[0038] The generally S-shaped puncture device and integral stent delivery device of the invention may incorporate an obdurator and/or a tip having a profile or features that minimise dissection. It is assumed that puncture from a needle is more likely to self-seal than a channel since upon withdrawal of the needle the cells will relax and a haemostatic plug will form.

[0039] The puncture needle is designed so that it is capable of deploying a stent through the thickness of an adult heart, assuming the myocardium thickness is 10 - 15mm.

[0040] The puncture needle, regardless of the material of which it is constructed, is radio-opaque or possesses obvious radio-opaque markers. It may be coated with a lubricious coating e.g. hydro-gel, Parylene. The stent may be manufactured from Nitinol or similar to offer resistance to the pressure of the beating heart that might otherwise plastically deform less resistant materials and to obviate the need for balloon deployment.

[0041] In the embodiment of the delivery device having the generally S-shaped configuration, the stent is deployed through an orifice (aperture) in the distal shoulder of the sigmoidal puncture needle.

[0042] The stent delivery device of the invention employs a removable sheath over the stent to prevent premature expansion and to maintain a low profile prior to deployment.

[0043] Percutaneous transluminal delivery of contrast media may be necessary to indicate the exact position of the artery.

[0044] Advantageously the puncture needle positioned at the distal end of the stent delivery device is designed so that it does not core tissue; instead the puncture needle has a natural inclination to push the muscle fibres apart enabling a clear incision to be formed. The puncture needle is designed so that it is capable of deploying a stent through the thickness of an adult heart, assuming the myocardium thickness is 10 - 15mm. Generally, the myocardium thickness is 10 - 15mm for healthy adults, however it could be thinner and possibly thicker for some conditions.

[0045] In a preferred arrangement, the puncture needle is formed from stainless steel or a stiff thin walled

high modulus plastic such as LCP. Ideally the puncture needle also contains radio-opaque markers. It is preferable for the puncture needle to be coated with a lubricous coating.

[0046] A "flat" profile push-pull wire may be used to manipulate the stent into position in the stent delivery device in both configurations. Ideally this wire is made from a spring steel or similar material, for example, Nitinol.

[0047] The present invention further provides a sheath mechanism which wraps around the stent while in a compressed position in the medical stent delivery system. Preferably the sheath mechanism prevents the stent from expanding. Advantageously the sheath mechanism is removed by unwinding when so desired allowing the stent to radially expand.

[0048] According to another aspect, the present invention further provides a plurality of various new types of stent which include anchoring means for anchoring the stent firmly in position, when deployed for use. These stents are suitable for use with the medical stent delivery devices of the present invention.

[0049] Advantageously, each of the plurality of stents provided for use with the present stent delivery devices has a different configuration, each configuration providing enhanced anchoring properties to prevent migration of the stent when in position at the treatment site.

[0050] Conveniently, the anchoring means comprises first and second anchoring sections proximate the proximal and distal ends respectively of said hollow cylindrical section.

[0051] The stents of the invention may comprise a hollow cylindrical body made with a plurality of interconnected rings, wherein the rings extend circumferentially around the hollow cylindrical body and the rings are connected by a series of link elements.

[0052] In a first embodiment, the stent has a cylindrical body with flared ends or flanged ends. Ideally the flared or flanged ends provide the means for anchoring the stent in position in the vessel. Thus, the first and second anchoring sections comprise first and second flared ends or alternatively, first and second flanges. It is preferable for the flared ends or flanged ends to be formed intergrally with the stent.

[0053] A second embodiment of the stent comprises a tapered cylinder having a first diameter at a first end thereof and having a second larger diameter at a second end thereof. Thus, the stent in this embodiment has a cylindrical body, wherein the diameter of a first end of the stent is substantially larger than that of a second end and the diameter of the body of the stent decreases gradually from that of the first end to that of the second end in a tapering effect. Therefore there is a gradual decrease in diameter of each interconnected ring from the widest at the first end to the narrowest at the second end over the body of the stent.

[0054] Alternatively, the stent may comprise a hollow cylindrical section having a first diameter and a hollow tapered section having a first end of said first diameter coupled to said hollow cylindrical section and having a second end of a second diameter larger than said first diameter. Thus, the stent in this embodiment has a cylindrical body, wherein the diameter of the first end of the stent is substantially larger than that of the second end and the body of the stent comprises two connected portions. Ideally the diameter of the interconnected rings of a first portion gradually decrease from the widest diameter at the first end of the stent to the narrowest diameter which is equivalent to the diameter of the second end of the stent. Ideally the diameter of the second portion has a constant diameter which is the diameter of the second end of the stent. Advantageously the two portions are fused together. Ideally the fusion point of the two portions is at the point where the diameters are equivalent to that of the narrowest second end diameter. Optionally the first and second portion may be formed integrally with one another.

[0055] It is preferable for the degree of reduction in the diameter of the interconnected rings in either of the second embodiments of the stent to be determined with regard to the diameter of the first and second ends and the distance between the largest diameter interconnected ring and the narrowest diameter interconnected ring of the stent. Advantageously the taper effect provides means for the stent to resist migration from the original treatment site in the vessel over a period of time.

[0056] In a third embodiment, the stent comprises a hollow central section having a first diameter; a first hollow tapered section having a first end coupled to said central section and having a second end of a second diameter smaller than said first diameter; and a second hollow tapered section having a third end coupled to said central section and having a fourth end of a third diameter smaller than said first diameter. Hence, the stent in this embodiment has a generally cylindrical body, wherein the diameter of opposed first end and second end of the stent are equivalent in size and the diameter of the central section of the body of the stent is larger than that of the first and second ends of the stent. Advantageously, the stent includes anchoring means that help prevent stent migration when in position at the treatment site.

[0057] In a fourth embodiment, the stent comprises a a hollow cylindrical section having a first end and a second end and a curved hollow tubular section coupled to said first end. Advantageously both the hollow cylindrical section and the curved tubular section have the same diameter. Ideally the curved hollow tubular section curves about an angle of 90°. Advantageously the angle of curvature is not limited to 90°, and any suitable angle of curvature can be used. It is preferable for the hollow cylindrical section and the tubular section to be formed integrally with each other. Alternatively, the two sections can also be fused together.

[0058] In yet a further, fifth embodiment, the stent has a channel in the cylindrical body of the stent. It is pref-

erable for the channel to be positioned in the body of the stent at either end of the stent. Advantageously the end at which the channel is positioned is sealed to provide extra protection for the treatment site. Ideally, the stent directs the flow of blood when in position at the treatment site.

[0059] In a sixth embodiment, the stent comprises two hollow cylindrical end sections connected with a flexible intermediate section (mid-section). Ideally the intermediate section of the stent comprises a ring or a plurality of rings and/or interlinking members which extend circumferentially around the diameter of the hollow cylindrical ends in a helical arrangement. This allows for variation in the thickness of the vessel when the stent is *in situ*.

[0060] In a seventh embodiment of the stent, the stent comprises two hollow cylindrical end sections connected by a flexible intermediate section. Ideally, the intermediate section comprises a hollow cylindrical body that has been compressed into a bellows arrangement, enabling the intermediate section to lengthen and shorten as required as a vessel in which the stent is placed expands and contracts.

[0061] Advantageously the plurality of stents described above can be either self-expanding, elastically resisting compression in a free state, or radially expandable where the stent is expanded using an expansion device such as a balloon catheter. Clearly, the sheath mechanism is not necessary if an expansion device is required to expand the stent.

[0062] Ideally the self-expanding stents are formed from a material which offers resistance to the pressure of a beating heart which pressure might otherwise plastically deform less resistant materials. Such materials include Nitinol, nickel free self-expanding alloys or self-expanding polymers. Advantageously the radially expandable stents are formed from stainless steel. The stents are not limited to these materials and any suitable material known to a person skilled in the art can be used.

[0063] Advantageously, the present invention also provides a plurality of stents comprising a hollow cylindrical body made out of a solid tubular material.

[0064] The invention will now be described with reference to the accompanying drawings, which show, by way of example only, different embodiments of the stent types and stent delivery devices of the invention.

[0065] In the drawings:

Figures 1 to 10 are side views of ten embodiments of stents of the invention;

Figure 11 is a cross-section side view of a first embodiment of a medical stent delivery system of the invention;

Figure 12 is a cross-section side view of a second embodiment of a medical stent delivery system of the invention;

Figure 13 is a perspective view of a second embodiment of the medical stent delivery system of Figure 12; and

Figure 14 is a perspective view of a sheath of the medical stent delivery system of the invention.

[0066] Referring initially to Figures 1 to 10, ten embodiments of stents indicated generally by reference numerals 1 to 10, inclusive are shown for use in and deployment from the stent delivery devices of the invention.

[0067] Figure 1 shows a cylindrical stent 1 which has the form of a known stent. The design of the stent can be varied appropriately to suit the requirements of its use. Thus, radial strength, provision of wall support, longitudinal/radial flexibility and geometric size can all be varied as required.

[0068] In Figures 2 and 3, there are shown two stents 2 and 3 each having a cylindrical body with flared ends 2a, 2b and with flanges 3a, 3b respectively. The flared ends 2a, 2b have the advantage of assisting in anchoring the stent in position in the myocardium and in the vessel, when in use. Provision of flanges 3a, 3b on the stent 3 has the benefit of providing an anchoring means for anchoring the stent 3 in the heart while also aiding in attaching the artery to the heart.

[0069] Figure 4 shows a stent 4 having a tapered body, which has the advantage that stent 4 resists migration of the stent when in use. Since movement of the stent is restricted to some degree by the vessel walls within which it has been placed, the likely direction of migration is in the direction of the left ventricle chamber; consequently the end of the stent/shunt with the wider diameter is placed in the vessel and the end with the narrower diameter placed in the heart. The provision of the tapered walls on stent 4 benefits blood flow dynamics when the stent is in use.

[0070] Figure 5 shows a stent 5, which has a tapered section 5a, and a cylindrical section 5b. The provision of the tapered section 5a on stent 5 allows stent 5 to resist migration in addition to benefiting blood flow dynamics.

[0071] Figure 6 shows stent 6 having a central section 6a which has the largest diameter and a tapered section on both sides of the central section 6a. The tapered sections on stent 6 provide anchoring means and also assist in improving blood flow dynamics when the stent 6 is in use.

[0072] Figure 7 shows a stent with a cylindrical body 7a having a curved tubular section 7b for placement inside the artery. The curved section 7b of stent 7 is used to direct blood flow from the left ventricle of the heart to the diseased blood vessel (artery) distal of the lesion. The curved section 7a has the further advantage that it protects the region of the blood vessel that is punctured when the stent delivery device punctures the blood vessel when deliverying the stent. The method of delivery

of the stent is described further below.

[0073] Figure 8 shows a stent 8 with channel 8a in the side wall 8b with the channel 8a being aligned in the direction of the blood flow to provide a blood flow path. The opposed end 8c of the stent 8 is sealed to protect the region of the blood vessel in which the puncture is made when the stent is being deployed by the stent delivery device of the invention.

[0074] Figure 9 shows a stent 9, with two cylindrical end sections 9a with a flexible intermediate section (mid-section) 9b to allow for variation in the thickness of the myocardium due to the contraction and relaxation of the beating heart. The flexible intermediate section 9b adopts a generally helical configuration.

[0075] Figure 10 shows a cylindrical stent 10, with an intermediate portion of the cylindrical body having a "bellows" configuration 10a, which configuration enables the stent to expand and contract when in position at the treatment site. Thus the "bellows" configuration provides stent 10 with the same advantage as the flexible intermediate section 9b provides to stent 9.

[0076] Referring now to Figure 11, a first embodiment of the medical stent delivery device 11 having a linear (straight) configuration will be described. The medical stent delivery device 11 comprises a hollow cylindrical body 100 with puncture needle 130, a stent 120 is positioned at the distal end within the hollow cylindrical body 100. The stent has a distal end 120a and a proximal end 120b. The stent delivery device 11 also includes an actuator means 110. The actuator means can be a manual plunger mechanism or an automated hydraulic or a LVDT type device. The actuator means, regardless of its mode of power, is required to actuate the expulsion of the stent. In this embodiment, the actuator 110 comprises a plunger mechanism for expelling the stent from within the hollow cylindrical tube by compression of a plunger 130a.

[0077] The procedure for using the medical stent delivery device 11 begins with the surgeon gaining access to the target vessel by a small incision in the chest cavity of the patient. An introducer may be used to provide an access port for surgical devices which the surgeon needs to use. This introducer is able to facilitate the surgeon's use of an endoscope with light source, a heart stabilising device such as the Medtronic EndoOctupus™, as well as the stent delivery device 11 or a puncture tube and various standard surgical tool for use in minimally invasive surgery such as suturing devices, probes, scissors, and stabilisers. The target vessel is then accessed through pericardial sac. Depending on which of the type of stent 1 to 10 is being used, one of the following surgical techniques numbered 11.1, 11.2 and 11.3 is then used:

First Possible Surgical technique for Use with Stent Delivery Device 11:

[0078] 11.1 The surgeon locally removes the artery from the surface of the heart and moves it slightly (3 - 5mm) to one side.

[0079] The sheathed puncture needle 130 positioned at the distal end of stent delivery device 11 is now introduced through the incision in the patient's chest wall, optionally through an introducer and into the heart wall until it pierces the wall of the left ventricle. Then the puncture needle 130 is advanced and passes into the left ventricle. A pressure-sensing device may be used to indicate when the puncture needle 130 has advanced into the left ventricle. Alternatively, this will be determined by the surgeon visually by noting blood flow through to the proximal end of the delivery device 11. The stent 120 is deployed into position in the inner myocardial wall using the actuator 110. When deployed, the distal end of the stent 120a is positioned in the inner wall of the myocardium and projects into the left ventricle while the proximal end 120b of the stent protrudes by about 3mm out from the outer wall of the myocardium. The proximal end 120b of the stent is prevented from expanding radially by use of a sheath mechanism (not shown). The surgeon now makes an incision in the underside of the occluded vessel on the side of the occlusion distal the heart and the surgeon places the proximal end 120b of the stent is inserted into this incision. Thus, a conduit or shunt is formed between the left ventricle and the artery, distal of the occlusion, thereby supplying an improved flow of oxygenated blood to the vessel (most likely, this vessel is an artery).

Second Possible technique for Use with Stent Delivery Device 11:

[0080] 11.2 In a variation of the technique described above in technique 11.1, the surgeon proceeds as described in technique 11.1, except that he uses a device for restricting the proximal end of the stent from expanding until it is positioned in the artery. Use of this restricting device allows for a smaller incision to be made in the artery. The stent may be designed so as to have a proximal end which facilitates this restriction, thereby further enabling the surgeon to require only a smaller incision then otherwise possible.

Third Possible technique for use with Stent Delivery Device 11:

[0081] 11.3 An alternative technique is also possible in which the stent delivery device 11 is advanced through the vessel (artery) without the surgeon having to move the vessel to one side. In this technique, the surgeon proceeds initially to access the target site as set out above in the paragraph preceding the description of the first technique 11.1. Then, instead of moving the artery to the side as in technique 11.1, the surgeon deploys the stent in a controlled manner such that the puncture needle 130 punctures the vessel at the side proximal to the surgeon and then passes through the

vessel and through the opposed wall of the artery and then through the myocardium. Thus, there are two incisions at opposed side walls of the artery with this technique. The actuator mechanism 110 is then activated so that the stent is delivered through the artery into the left ventricle with the stent distal end 120a in the left ventricle and the stent proximal end 120b remaining in the artery thereby enabling blood flow from the left ventricle through the stent and into the vessel (artery) at a point distal to the lesion. The incision on the upperside of the vessel (i.e. the side of the vessel proximal to the surgeon) is then closed by a known method e.g. a suture or fibrin plug. By using smaller diameter stents, it is possible to reduce further the outer diameter of the delivery device and this allows for reduction in the size of the puncture wound even more. With a smaller diameter stent, there may be a necessity to place one or more additional stents to obtain sufficient blood flow.

[0082] Referring now to figures 12 and 13, a second embodiment of the medical stent delivery device 12 having a curved, generally S-shaped configuration will be described. The curved, generally S-shaped delivery system 12 comprises an arcuate hollow cylindrical body 140 which has a generally S-shaped configuration including a first arcuate section (elbow) 144 and a second arcuate section (elbow) 145. The hollow cylindrical body 140 includes a puncture device 130, a stent 120 positioned at the distal end within the hollow cylindrical body 140 and an actuator means 150 comprising a push-pull wire which is removably engaged with the distal end 120b of the stent 120. There is a second puncture device 160 positioned at the proximal end 120b of the stent 120. The hollow cylindrical body 140 includes an orifice 142 located at an arcuate portion of the hollow cylindrical body i.e. at the "elbow 144" of the hollow cylindrical body located in the region accessible to an occluded vessel 180.

[0083] As before, the S-shaped delivery device 12 gains access to the treatment site via a minimally invasive type incision made by a surgeon in the patient's chest, close to the treatment site. Usually another instrument is used to make this incision. In use, the stent delivery device 12 punctures the artery from underneath and thus has the advantage of only one perforation in the artery.

[0084] There are three possible alternative methods by which the surgeon can use the second embodiment of the delivery device 12, namely techniques 12.1, 12.2 and 12.3 described below.

[0085] This device 12 is used initially in a similar way as the first embodiment of the device 11 in that it is introduced through an introducer via an incision in the patient's chest.

First technique for use with delivery device 12:

[0086] 12.1 In the first technique, the device 12 is introduced beside the artery 180 at a point distal to the lesion as shown in Figure 12 and the puncture device 130 at the distal end of the delivery device 12 makes an incision through the myocardium 170. A pressure-sensing device can be used to indicate when the distal end of the delivery system 12 has advanced sufficiently through the myocardium into the heart chamber. A heart stabilization device such as Medtronic EndoOctupus™ is used to hold the heart surface in the region of the operating site. Once in position, the stent 120 and its retaining sheath (not shown) are advanced out of the delivery device through the myocardium and into the artery.

[0087] The stent 120 is deployed using the pull-push wire 150. Before deployment of this wire, the stent 120 is positioned within the heart to the inner side of the myocardium 170. The stent 120 is prevented from expanding radially by use of a sheath mechanism (not shown). The proximal end 120b of the stent 120 has a puncture device 160 which forms an incision in and through the myocardium on deployment of the wire 150 in the direction of the arrow in Figure 12. Thus, the stent 120 is drawn through the orifice 142 and through the myocardium and then the wall of the diseased occluded vessel 180. The end of the wire 150 which engages the distal end of the stent 120 has a 'flat' or 'U' profile shape which provides maximum force transmission for moving the stent within the restricted bore of the delivery device 12. The push-pull wire 150 may be made from a spring steel or similar material e.g. Nitinol. Once it is established that the stent 120 is in the deployed position in the myocardium and the vessel 180, the sheath is removed, thereby enabling the stent 120 to expand radially forming a conduit between the heart and the vessel.

[0088] As shown in figure 12, the generally S-shaped device 12 is pushed down sufficiently into the ventricle until the orifice 142 at the first elbow 144 of the hollow cylindrical body 140, is below the inner wall of the myocardium 170. This allows the puncture device 160 and stent 120 to be pulled upwardly and in through the lumen of the vessel 180 to revascularized.

[0089] It is envisaged that the puncture device 160 may be formed separately from the stent and that it be attached to the distal end of the wire 150. This allows the puncture device 160 to be withdrawn by means of the wire 150 following deployment and expansion of the stent 120.

Second technique for use with delivery device 12:

[0090] **12.2** In the second possible method, the vessel is moved to one side by the surgeon and the needle is inserted into the myocardium at the location where the vessel was positioned. This allows for a sharper bend on the S-shaped puncture needle and thus enables a straight travel path for the stent from the myocardium up into the vessel. Once positioned, the vessel is moved back into its original position and the stent and sheath advanced as described previously. Once positioned in

the vessel the sheath can be removed and the stent deployed.

Third technique for use with delivery device 12:

[0091] **12.3** A potential third technique of the S-shaped puncture device 12 utilises the method as described in technique 12.2 but the device 12 incorporates a new sheath mechanism 12 which wraps around the stent 120 while in a compressed position in the delivery device 12. The sheath mechanism prevents the stent 120 from expanding until desired. To release the stent, the sheath is unwound off the stent. This requires a slight modification to the puncture needle. Figure 14 illustrates the modified delivery device with a slit in the distal section of the tube to allow the stent to be deployed therefrom upon retraction/unwinding of the sheath.

[0092] A potential problem of retrograde blood flow may arise with the above described devices. Retrograde flow arises where the blood uses the conduit created by the stent as a passage back into the left ventricle. This problem can be overcome by placing a one-way valve in the conduit which only allows blood to flow from the left ventricle to the vessel (artery). Another potential method of overcoming the problem of retrograde flow is to seal off the lesion fully. This could be achieved by placing a mechanical blocking device in the lesion. It may be possible to seal off the lesion by suturing the artery closed distal to the lesion. It may also be possible to place a fibrin block/patch in the lesion to prevent the retrograde blood flow.

[0093] It will, of course, be understood that the invention is not limited to the specific details as herein described, which are given by way of example only, and that various alterations and modifications may be made without departing from the scope of the invention as defined in the appended claims.

Claims

1. A delivery device (11, 12) for delivering a medical stent (120) to a treatment site for forming a conduit between a blood vessel and a heart chamber, the delivery device comprising:

   a hollow cylindrical body (100, 140) having a proximal end and a distal end, said cylindrical body (100, 140) being capable of receiving the stent (120); and

   an actuator (110, 150) for expelling the stent from said body to form the conduit, whereby, in use, the stent is positioned within the body (100, 140) and on activation of the actuator means (110, 150), the stent is expelled from the cylindrical body to form the conduit.

2. A device (11) according to claim 1 wherein said actuator (110) comprises a plunger (110, 130a).

3. A device (11) according to claim 2 wherein said plunger (130a) is manually activated.

4. A device (11) according to claim 2 wherein said plunger (130a) is hydraulically activated.

5. A device (11, 12) according to Claim 2 further comprising a first puncture means (130) deployed proximate the distal end of said body (100, 140).

6. A device (11, 12) according to Claim 5 wherein said first puncture means (130) is made from a plastics material.

7. A device (11) according to any one of Claims 1 to 6 wherein said body (100) is substantially straight.

8. A device (12) according to any one of Claims 1 to 6 wherein said body (140) is substantially curved.

9. A device (11) according to Claim 8 wherein said body (140) comprises a substantially elbow-shaped curve (144).

10. A device (12) according to Claim 9 wherein said body (140) is S-shaped.

11. A device (12) according to any one of Claims 8 to 10 further comprising an opening (142) in said body (140) proximate said elbow-shaped curve (144) through which opening (142) the stent (120) is deployed.

12. A device (12) according to any one of Claims 8 to 11 further comprising a second puncture means (160) deployed proximate a proximal end (120b) of the stent (120).

13. A device (12) according to any one of Claims 8 to 12 wherein said actuator (150) is a push-pull wire (150).

14. A device (12) according to Claim 13 wherein said push-pull wire (150) has a substantially flat profile.

15. A device (12) according to Claim 14 wherein said push-pull wire (150) has a generally U-shaped profile and resides adjacent an internal wall of said body (140).

16. A device (12) according to any one of Claims 13 to 15 wherein said push-pull wire (150) is manufactured from spring steel.

17. A device (11, 12) as claimed in any one of the pre-

ceding claims wherein the actuator (110, 150) is positioned at least partially within said body (100, 140).

18. A device (11, 12) according to any one of the preceding claims wherein said stent (120) is radially expandable.

19. A device (11, 12) according to any one of the preceding claims wherein said stent (120) is self-expanding.

20. A device (11, 12) according to any one of the preceding claims wherein said stent (120, 2, 3, 4, 5, 6, 7, 8, 9 10) comprises:

a hollow cylindrical section having a proximal end and a distal end; and

anchoring means (2a, 2b;3a;4a;5a;5b;6a;7a; 7b;8b;9a, 9b;10a, 10b) for preventing migration of the stent when in position at the treatment site

21. A device according to Claim 20 wherein the anchoring means (2a,2b) comprises:

first and second anchoring sections (2a, 2b) proximate the proximal and distal ends respectively of said hollow cylindrical section.

22. A device according to Claim 21 wherein said first and second anchoring sections (2a,2b) comprise first and second flared ends (2a, 2b) respectively.

23. A device according to Claim 21 wherein said first and second anchoring sections comprise first and second flanges (3a, 3b) respectively.

24. A device according to Claim 20 wherein said stent (4) is a tapered cylinder (4a) having a first diameter at a first end thereof and having a second larger diameter at a second end thereof.

25. A device according to Claim 20 wherein said stent (5) comprises:

a hollow cylindrical section having a first diameter (5b); and
a hollow tapered section having a first end of said first diameter (5b) coupled to said hollow cylindrical section and having a second end of a second diameter (5a) larger than said first diameter (5b).

26. A device according to Claim 20 wherein said stent (6) comprises:

a hollow central section (6a) having a first diameter;

a first hollow tapered section having a first end coupled to said central section (6a) and having a second end of a second diameter smaller than said first diameter; and

a second hollow tapered section having a third end coupled to said central section (6a) and having a fourth end of a third diameter smaller than said first diameter.

27. A device according to Claim 20 wherein said stent (7) comprises:

a hollow cylindrical section having a first end and a second end; and

a curved tubular section (7b) coupled to said first end.

28. A device according to Claim 20 wherein said stent (8) comprises:

a hollow cylindrical section having a first sealed end; and

a channel (8a) through a sidewall of said first cylindrical section proximate said first sealed end.

29. A device according to Claim 20 wherein said stent (9, 10)comprises:

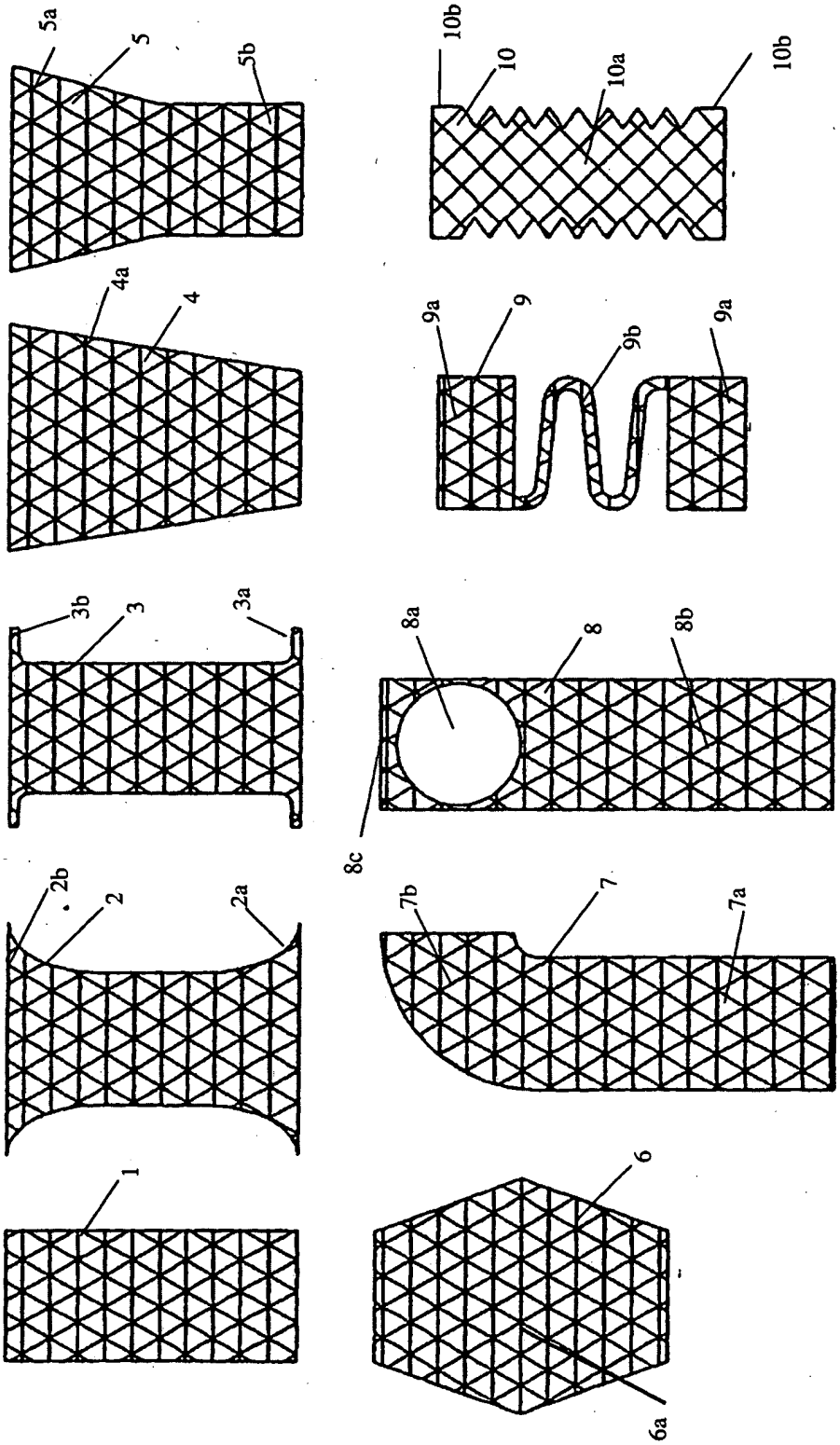
a first hollow cylindrical section (9a; 10b);

a second hollow cylindrical section (9a; 10b); and

a flexible intermediate section (9b; 10a) coupled between said first and second hollow cylindrical sections (9a).

30. A device according to Claim 29 wherein said flexible intermediate section (9b) is helical.

31. A device according to Claim 29 wherein said flexible intermediate section (10a) is configured as a bellows.


5a
5
5b
10b
10
10a
10b
4a
4
9a
9
9b
9a
3b
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7a
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6a

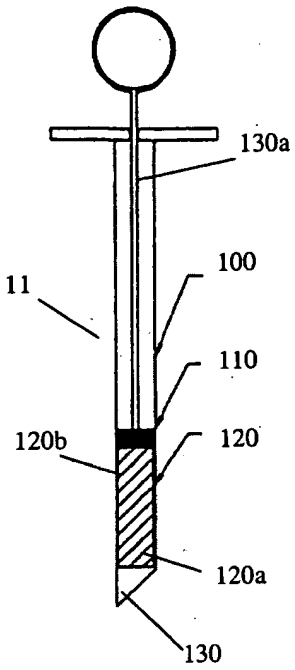

FIGURE 11

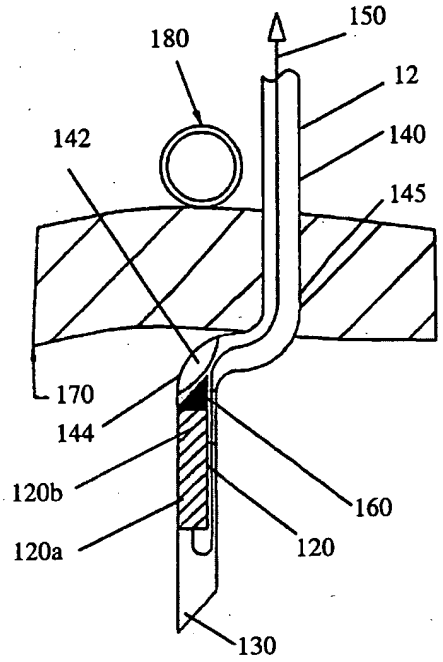

FIGURE 12

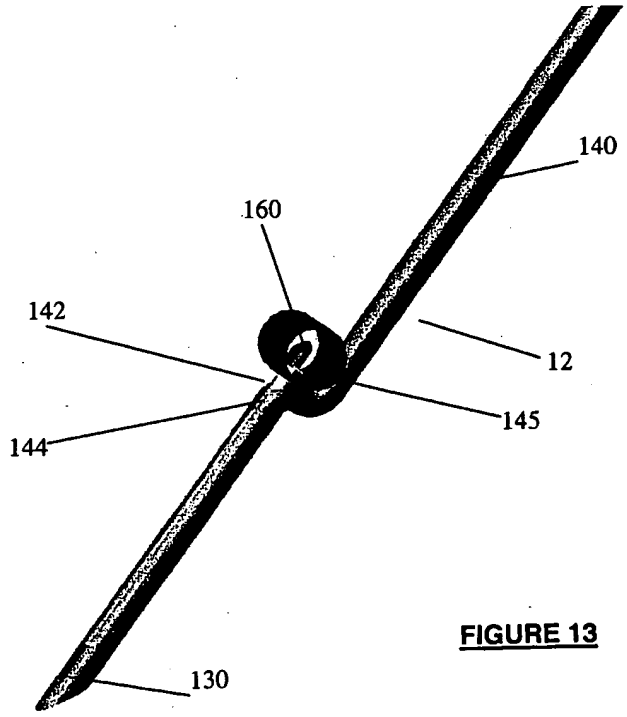

FIGURE 13

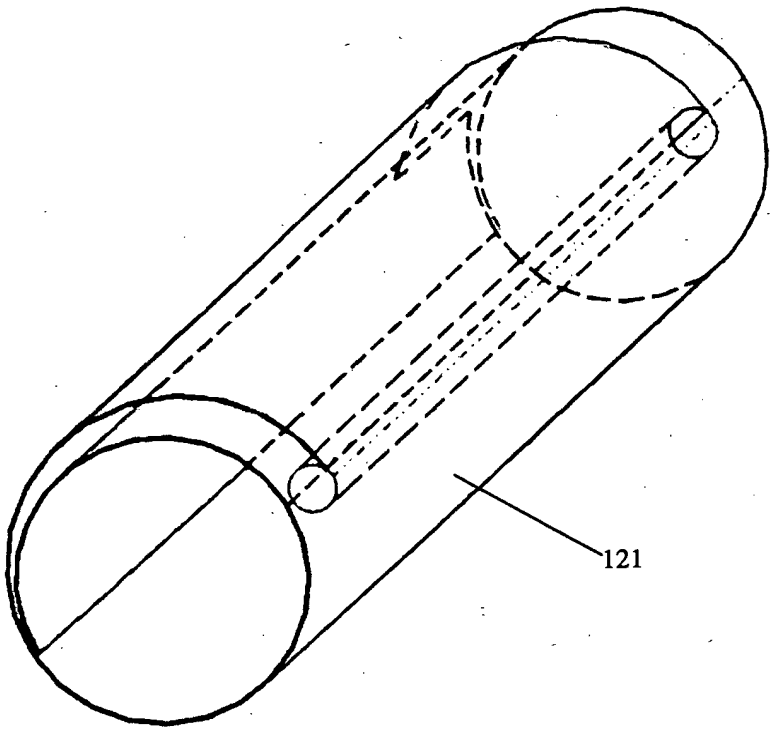

FIGURE 14

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Place of search	Date of completion of the search	Examiner
Munich	8 November 2004	Newman, B

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